

REMARKS

I. CLAIMS STATUS

A. Status of Claims Prior to this Amendment

This amendment is in response to the non final office action having a mail date of 2/23/2007. The "DISPOSITION OF CLAIMS" section in that office action contains an error. That section states that claims 103 and 177-215 are pending, that claims 103 and 192-215 are withdrawn, and that claims 177-191 are rejected. The error is that the "DISPOSITION OF CLAIMS" section does not identify the pendency or status of claims 1-101. Claims 1-101 were originally filed and never canceled.

In fact, claims 1-101, 103, and 177-215 were pending, claims 1-101, 103, and 192-215 had been withdrawn by the examiner, and claims 177-191 had been examined and rejected.

Prior to this amendment, claims 1-101, 103, and 177-218 were pending.

Prior to this amendment, claims 1-101, 103, and 192-215 were withdrawn by the examiner.

Prior to this amendment, claims 177-191 were rejected.

B. Amendment to Claims

This amendment cancels all claims previously pending and presents new claims 216-226. Claim 216 is the independent claim.

The examiner indicated in a telephone call with the undersigned on 4/10/2007, after the examiner reviewed claims 216-226, that these new claims would be examined if filed with a Request for Continued Examination.

II. WITHDRAWAL OF CLAIMS 103 AND 192-215

In items 1 and 2, the office action states that:

1. Newly submitted claims 103 and 192-215 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claims pertain to a device which contains features not found in the originally claimed invention, for example: two reflective surfaces to produce a base focus, two reflective surfaces and a diffractive pattern to produce an additional focus, and two reflective surfaces

which determine a negative lens spherical aberration.

2. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 103 and 192-2 15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP 5 82 1.03.

In response, the applicant cancels the withdrawn claims.

III. REJECTIONS OF CLAIMS 177, 178, 181, 182,184, 186, 187 and 191 FOR OBVIOUSNESS-TYPE DOUBLE PATENTING

In item 9, the office action states that:

9. Claims 177, 178, 181, 182,184, 186, 187 and 191 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 11-34 and 43 of copending Application No. 10/1 19,611 in view of Lee et al. (U.S. Patent Number 5,699,142). The copending Application claims every feature of the above cited claims but fails to disclose a base focus and an additional focus. Lee et al. discloses the use of a multifocal lens for use in the eye. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of a multi-focal lens, as taught by Lee et al. to a diffractive lens, as per Applicant. Since it is well known in the art to use multi-focal lenses to correct vision deficiencies the above mentioned claims are not patentable over the copending application.

In response, the applicant submits that the rejection was improper because the claims of this application are not obvious in view of application 10/119,611 in view of Lee. In fact, application 10/119,611 is entitled "NOVEL CYCLOHEXENYL PHENYL DIAZEPINES VASOPRESSIN AND OXYTOCIN RECEPTOR MODULATORS " and it is directed to subject matter completely unrelated to this application. Application 10/119,611 does not disclose the elements of a lense upon which the office action relies. That is, application 10/119,611 does not disclose any "feature of the above cited claims" and it also does not disclose "a base focus and an

additional focus." Therefore, the rejections relying upon application 10/119,611 are improper and should be withdrawn.

Citation to 10/119,611 is apparently a clerical error. The applicant believes the examiner intended to refer to 10/119,661, now United States patent 6,830,332.

In an effort to move this application forward, and believing that this was merely a clerical error, the applicant submits herewith a terminal disclaimer by an attorney of record in this application over application 10/119,661, now United States patent 6,830,332. The terminal disclaimer precludes a rejection for obviousness-type double patenting over 10/119,661, now United States patent 6,830,332, in view of U.S. Patent Number 5,699,142 to Lee et al.¹

IV. REJECTIONS OF CLAIMS 177-191 UNDER 35 USC 103 - SUMMARY

In item 12, the office action states that:

12. Claims 177-191 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piers et al. (International Publication Number WO 021084381) in view of Lee et al. (U.S. Patent Number 5,699,142). Piers et al. discloses an ophthalmic lens however Piers et al, fails to disclose a multifocal ophthalmic lens comprising an apodization zone or echelettes. Lee et al, teaches a multifocal lens comprising both an apodization zone and echelettes (col. 2, lines 27-44). It would have been obvious to one of ordinary skill in the art to combine the teaching of a multi-focal lens, as taught by Lee et al., to an ophthalmic lens as per Piers, the motivation to combine being that a multi-focal lens aides persons with visual deficiencies by providing vision correction for varying distances, as found in Lee et al. (col. 1, lines 49-67).

In response, the applicant first shows that WO 021084381 is not available under 35 USC 102(b) as prior art for claims 216-226 by showing support for these claims in priority application 60/430,515. Second, the applicant shows actual reduction to practice of independent claim 216 prior to the publication date of WO 021084381. Thus, the applicant shows that WO 021084381 is not prior art under 35 USC 102(a) to independent claim 216, and therefore also not 35 USC

¹The terminal disclaimer by an attorney of record in this application over the patent issued from application 10/119,661, which is United States patent 6,830,332, is attachment 1.

102(a) prior art to all of the dependent claims.

V. WO 021084381 IS NOT 102(B) PRIOR ART

A. Summary

This application claims priority to provisional application 60/430,515 filed 12/3/2002.² Claim 216-226 find written description and enabling support in 60/430,515, as shown in the charts and showings below. Therefore, claim 216-226 are entitled to the 12/3/2002 filing date of the 60/430,515 application. 35 USC 119(c).

The 12/3/2002 filing date of the 60/430,515 application is within one year of the 10/24/2002 publication date of WO 021084381. Therefore, WO 021084381 is not statutory prior art under 35 USC 102(b) to claim 216-226. 35 USC 102(b); 35 USC 120.

The following chart and discussion shows where support exists in provisional application 60/430,515 for claims 216-226. Please note that the support cited in 60/430,515 is representative. That is, the cited support is not necessarily the sole support in 60/430,515.

B. Support in 60/430,515

CLAIM 216

SUPPORT IN 60/430,515

<p>216. (New) A diffractive multi focal intraocular lens comprising:</p>	<p>Page 1, "Technical field of the invention" section states that the present invention relates "in more detail to a multifocal intraocular lens with reduced aberrations".</p> <p>Page 18 second full paragraph describes some materials and manufacturing methods for the claimed multifocal ophthalmic lens.</p>
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²A copy of application 60/430,515 is attachment 2.

<p>a first refractive surface; a second refractive surface; a diffractive pattern on at least one of said first refractive surface and said second refractive surface;</p>	<p>Page 6 first full paragraph lines 6-15 disclose a "bifocal diffractive lens" which is "a combination of a conventional refractive lens and a diffractive lens..." and the "diffractive lens consists of a series of radial rings or "zones" of decreasing width"; that "the diffractive lens may be formed on the anterior or posterior surface of the conventional lens"; that the light distribution is determined by the "step height" (diffractive feature depth) of the steps; and that the diffractive power add is determined by the "diameters of the diffractive zones".</p>
<p>wherein said first refractive surface, said second refractive surface, and said diffractive pattern result in a base focus and an additional focus; and</p>	<p>Page 6 first full paragraph lines 6-15 disclose the conventional refractive lens "focused to infinity and the latter [diffractive lens] for near vision," that the diffractive pattern step height determines light distribution, and that the diffractive pattern zone width determines the diffractive add power for "near field focus".</p>

<p>wherein at least one of said first refractive surface and said second refractive surface has an aspheric component to its shape.</p>	<p>Page 7 lines 1-2 state that "the lens has at least one surface described as a nonsphere or other conoid of rotation." Page 10 lines 1-14 state that the method comprises determining if the bifocal lens provided "sufficient reduction in wavefront aberrations" and if not, "[r]emodeling the lens" using as at least one of the following design parameters: lens "anterior surface shape and central radius"; lens "posterior surface shape and central radius"; "thickness"; "refractive index"; and "diameters and step height of the diffractive zones" so that the shape of the surface shape "deviates from being spherical." This passage also cites to "optical design software packages" that were "available" for the modeling. Page 21 lines 17-18 refer to the 550 nanometer reference wavelength. Original claim 9 in 60430515 claims "selecting a suitable aspheric component" for the anterior surface of the IOL.</p>
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DEPENDENT CLAIM

SUPPORT IN 60/430,515

<p>217. (New) The lens of claim 216 wherein said aspheric component is a prolate shape.</p>	<p>Page 14 lines 23-26 in 60430515 state that "Accordingly a bifocal intraocular lens suitable to improve visual quality by reducing at least spherical aberration for at least one focus for a cataract patient based on an average corneal value will have a prolate surface following the formula above."</p>
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<p>218. (New) The lens of claim 216 wherein said aspheric component reduces spherical aberration of a wavefront that passes through said lens.</p>	<p>The paragraphs spanning pages 14 and 15 in 60430515 states that "Since the cornea generally produces a positive spherical aberration to a wavefront in the eye, a bifocal intraocular lens for implantation into the eye will have negative spherical aberration terms while following the mentioned prolate curve. As will be discussed in more detail in the exemplifying part of the specification, it has been found that an intraocular lens that can correct for 100% of a mean spherical aberration has a conical constant (cc) with a value of less than 0 (representing a modified conoid surface). For example, a 6 mm diameter aperture will provide a 20 diopter lens with conical constant value of about - 1.02.</p> <p>In this embodiment, the bifocal intraocular lens is designed to balance the spherical aberration of a cornea that has a Zernike polynomial coefficient representing spherical aberration of the wavefront aberration with a value in the interval from 0.0000698 mm to 0.000871 mm for a 3mm aperture radius, 0.0000161 mm to 0.00020 mm for a 2 mm aperture radius, 0.0000465 mm to 0.000419 mm for a 2,5 mm aperture radius and 0.0000868 mm to 0.00163 mm for a 3,5 mm aperture radius using polynomials expressed in table 1."</p>
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219. (New) The lens of claim 218 wherein, when said wavefront is represented as a series of Zernike polynomials, a Zernike Z11 term describing said wavefront is reduced when said wavefront passes through said lens.	Page 25 lines 15-18 (not counting lines of tables) in 60430515 state that "Table 5 shows a large reduction of aberration represented by the coefficients Z11 and no significant reduction of coefficient Z22 and Z37, indicating that Zernike term Z11 was minimized.... ."
220. (New) The lens of claim 219 wherein said series of Zernike polynomials comprises up to at least fourth order terms.	See the discussion of support for claim 219.
221. (New) The lens of claim 216 wherein said lens comprises at least one of a silicone, a hydrogel, and an acrylate.	Claims 154 and 155 in 60430515 claim silicone and hydrogel. Page 18 in the paragraph spanning pages 18 and 19 discloses silicone, a hydrogel, and an acrylate.
222. (New) The lens of claim 216 wherein the same refractive surface defines both said aspheric component and said diffractive pattern.	Page 11 lines 9-11 in 60430515 state that "The diffractive pattern of the bifocal lens may be formed independently of the lens surface that is modeled to reduce aberrations of the optical system, but it could also be formed on the same lens surface."
223. The lens of claim 216 wherein an add power for said additional focus is between 2 and 6 diopters.	Page 14 lines 4-7 in 60430515 state that "Preferably the refractive power for the base focus of the lens is less than or equal to 34 diopters and the additional focus between 2 and 6 diopters."

224. (New) The lens of claim 216 wherein an add power for said additional focus is 3 to 4 diopters.	Page 21 lines 5-9 in 60430515 state that "Throughout the example the light distribution between the two foci was chosen to be 50%:50%, and the target power add for near vision was +4D. Other light distributions can be chosen, without changing the principles of how the methods work. In practice, light distribution between 70%:30% to 30%:70% and near vision add between 3 and 4 diopters have been on the market. But also outside these ranges the methods should be applicable. "
225. The lens of claim 216 wherein a light distribution between said base focus and said additional focus is between 70%:30% to 30%:70%.	See support for claim 224.
226. (New) The lens of claim 216 wherein a light distribution between said base focus and said additional focus is 50%:50%.	See support for claim 224.

C. Support from the Examples

Moreover, the examples in 60/430,515 show that all claim limitations find support in 60/430,515, for example with reference to example 3.

For Example 3 spanning pages 24-27 see the following:

"A diffractive multifocal ophthalmic lens" - Page 25 lines 1-4 (biconvex lens having specified dimensions, diffractive profile on posterior surface, anterior surface aspherized).

Reduced spherical aberration compared to corneal spherical aberration - Page 25 lines 3-5 (optimizing jointly near and far foci) and page 25 lines 8-10 (modifying posterior surface to minimize Z11, Z24, and Z37, the lowest and higher order spherical aberrations of the eye lens system).

The "diffractive profile". - The examples including example 3 relate back to earlier disclosure for the diffractive profile. See page 20 second full paragraph at line 8 to page 21 line

2 describing by formula for the diffractive profile and indicating that the diffractive profile does not affect the calculation of the asphericity that minimizes aberration (stating that the diffractive profile is "not relevant for the working principles" of the calculations of the asphericity.)

Thus, the claims are all supported by the disclosure of 60/430,515. Therefore, WO 021084381 is not 35 USC 102(b) or 102(b)/103 prior art to claims 216-226.

**VI. WO 021084381 IS NOT 102(A) PRIOR ART TO INDEPENDENT CLAIM 216 -
PROOF OF PRIOR INVENTION**

A. Introduction

Second, the applicant files herewith a declaration of inventor Henk Weeber under 37 CFR 1.131 showing that inventions defined by the independent claim 216 were reduced to practice prior to the publication date of WO 021084381.³ WO 021084381 published October 24, 2002.

Reduction to practice exists when it has been demonstrated that the invention is suitable for its intended purpose.

Reduction to practice follows conception. To show actual reduction to practice, an inventor must demonstrate that the invention is suitable for its intended purpose. Scott v. Finney, 34 F.3d 1058, 1061, 32 USPQ2d 1115, 1118 (Fed. Cir. 1994). Depending on the character of the invention and the problem it solves, this showing may require test results. *Id.* at 1062; Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 550, 16 USPQ2d 1587, 1592 (Fed. Cir. 1990). Less complicated inventions and problems do not demand stringent testing. Scott, 34 F.3d at 1062. In fact, some inventions are so simple and their purpose and efficacy so obvious that their complete construction is sufficient to demonstrate workability. *Id.*; King Instrument Corp. v. Otari Corp., 767 F.2d 853, 861, 226 USPQ 402, 407 (Fed. Cir. 1985), cert. denied, 475 U.S. 1016, 89 L. Ed. 2d 312, 106 S. Ct. 1197 (1986). [Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578; 1996 U.S. App. LEXIS 6078, ____; 38 USPQ2d 1288, ____ (Fed. Cir. 1996).]

Showing an invention is suitable for its intended purpose may require testing to show that

³The declaration of inventor Henk Weeber under 37 CFR 1.131 is attachment 3.

the invention works for its intended purpose.

In all of the cases in which this court has reviewed whether sufficient and proper testing had occurred to establish reduction to practice, we have taken pains to point out that the nature of the testing required depends on the particular facts of each case. A certain amount of "common sense" must be applied in determining the extent of testing required. Depending on its nature, the invention may be tested under actual conditions of use, or may be tested under "bench" or laboratory conditions which fully duplicate each and every condition of actual use, or, in some cases, may be tested under laboratory conditions which do not duplicate all of the conditions of actual use. In instances where the invention is sufficiently simple, mere construction or synthesis of the subject matter may be sufficient to show that it will operate satisfactorily. In all such cases, the evidence must establish a relationship between the subject matter involved, the test conditions and the intended functional setting of the invention. White v. Lemmerman, 52 CCPA 968, 341 F.2d 110, 144 USPQ 409; Paivinen v. Sands, 52 CCPA 906, 339 F.2d 217, 144 USPQ 1. [Gordon v. Hubbard, 52 C.C.P.A. 1598, 1604, 347 F.2d 1001, 1965 CCPA LEXIS 320, ___, 146 USPQ 303, ___ (CCPA 1965).]

Claim 216 reads on the designed and prototyped lenses. The evidence in support of these conclusions is discussed below.

The report referred to in the Weeber declaration shows that the inventors showed by design, calculation, manufacture, and then testing, that the prototype lenses had optical performance in terms of reduction in visual aberrations as good or better than prior art lenses. Thus, "the evidence ... establish[es] a relationship between the subject matter involved, the test conditions and the intended functional setting of the invention" showing that the claimed lenses were "suitable for their intended purpose." Gordon v. Hubbard, *supra*.

The Weeber declaration refers to a report, a copy of which having dates redacted is attached to the Weeber declaration and submitted as attachment 4.⁴ The date of the original

⁴A copy of the report referred to in the Weeber 131 declaration, with dates redacted, is attachment 4.

report is prior to October 24, 2002.

The report discusses design, analysis, manufacture, and testing of the manufactured prototypes. The prototypes were bifocal ophthalmic lens including all of the elements of independent claim 216. The report, as explained in the Weeber declaration, shows that the inventors believed that the prototypes (1) included the limitations of independent claim 216 and (2) functioned to perform their intended purpose.

B. Independent Claim 216 Reads on the Designed and Tested Lenses

The following chart show that the lenses designed and tested met the limitations of independent claim 216. Please note that the selected portions of the report in the chart below are representative.

CLAIM 216**DISCLOSURE IN THE REPORT**

<p>216. (New) A diffractive multi focal intraocular lens comprising:</p>	<p>Page 1 title "Bifocal foldable lens design based on corneal wavefront aberration"</p> <p>Page 3 section 1 and page 9 section 4.1 describes the prototype designs of the optical surfaces, and lens formed from HRI silicon material.</p>
<p>a first refractive surface; a second refractive surface; a diffractive pattern on at least one of said first refractive surface and said second refractive surface;</p>	<p>Page 3 section 1 identifies the diffractive profile on the posterior lens surface. Page 5 figure 1 show an insert showing the zone widths and step heights specified in the diffractive profile formula on that page. Page 6 section 3.1.2 specifies the light distribution determined by the step height. Page 6 section 3.1.3 specifies the power add is determined by the diameters of the diffractive zones.</p>
<p>wherein said first refractive surface, said second refractive surface, and said diffractive pattern result in a base focus and an additional focus; and</p>	<p>Page 3 section 1 refers to the near and far field vision.</p>
<p>wherein at least one of said first refractive surface and said second refractive surface has an aspheric component to its shape.</p>	<p>Page 3 section 1 first paragraph refers to the lens design correcting for corneal aberration by providing a negative spherical aberration equal and opposite in sign to the corneal spherical aberration, the negative spherical aberration induces by "an aspherical anterior surface".</p>

Thus, the report shows that all of the elements of independent claim 216 were contained in the prototypes.

C. The Evidence Showing that Designed and Tested Lenses Were a Reduction

To Practice of Independent Claim 216

The following refers to the redacted report referred to in the Weeber declaration.

Page 9 section 4 and page 10 Figure 5 specify the prototype lens designs. Page 9 section 4 specifies that the prototype intraocular lens design included a refractive surface contoured to include a diffractive pattern with step height and ring diameter values adapted to silicone HRI material to provide near and far foci, and another lens surface optimized for symmetrical Zernicke terms for near and far vision. Thus, the report shows that the intraocular lens design had the claimed first refractive surface, second refractive surface, diffractive pattern, and resulted in a base focus and an additional focus. Figure 17 on page 18 shows coefficients of CC, AD, and AE for aspheric terms of an equation defining the anterior surface of the IOL. CC (the conic constant), AD, and AE are referred to on page 7 in section 3.1.6 with respect to an algorithm for determining optimum aspheric components of the surface shape of the IOL. Thus, the report shows that the intraocular lens design had the claimed refractive surface having an aspheric component to its shape. Weeber Declaration paragraph 6.

Page 10 Figure 4 specifies the theoretical performance of the prototype lens designs. Figure 4 shows that the aspheric designs provide far and near foci wavefront aberration values that are better than for a spherical design. Weeber Declaration paragraph 7.

Page 13 section 4.3 reports on optical performance testing of actual prototypes based upon the prototype designs. This section of the report states that "all results showed that the lenses were close to the design in the sub-micron range (average deviation from step height 0.04 micrometer)" indicating no problem in fabrication. Weeber Declaration paragraph 8.

Pages 13 to 17 contain various measurements and comparisons of the prototype aspheric lenses to a spherical bifocal lens. The report states in this respect on page 15 that "the results show that the optimized top and the Z9000 top [sic; prototypes] have comparable performance in terms of MTF. At 5 mm they are much better than model 811E." At page 17 the report states that add power is "very well on target" and that the far power "is a little off and needs fine-tuning." On page 17, section 4.3.5 identifies the desired "fine tuning." Weeber Declaration paragraph 9.

On page 18, section 5 is entitled "DISCUSSION," and it states that the "report shows that the Tecnis Z9000 design principles can be successfully applied on bifocal lenses" and that the "improvement of the ZM001 [sic; design prototype], compared to model 811E is significant ... for the larger pupils." Weeber Declaration paragraph 10.

The report attachment 4 was the culmination of work testing a bifocal variation of the

Z9000 lens. The design and testing was successful, and it indicated to Dr. Weeber that the designed lenses worked for their intended purpose of providing near and far focal points. Weeber Declaration paragraph 11.

VII. WO 021084381 IS NOT A 102(A) PRIOR ART TO DEPENDENT CLAIMS 216-228

Dependent claims that depend from an independent claim for which a reference has been antedated likewise antedate the reference. In re Spiller, 500 F.2d 1170, 1176-77, 182 USPQ 614, 619 (CCPA 1974);

Many dependent claims...raise the question whether the situation in Stryker [435 F.2d 1340, 168 USPQ 372 (CCPA 1971)], where the differences between the claimed invention and what the reference and affidavits showed were "so small as to render the claims obvious" to one skilled in the art in view of a single reference, ought to be extended to a situation where part or all of the differences are rendered obvious, not merely by the knowledge of one skilled in the art[,] but by other references available as of the date of the alleged [actual] reduction to practice. This court has recently answered that question in the affirmative, at least when a single other reference is involved, in In re Dardick, 496 F.2d 1234, 181 USPQ 834 (CCPA 1974), and we see no reason to distinguish the situation where two other references are used. As we noted in Dardick, the reference--or the references--are merely used to show what one skilled in the art would be expected to know as of the date of the reference which has been removed. The only additional caveat which ought to be added is that the affidavit showing must still establish possession of the invention and not just of what a reference happens to show if this is "wholly outside" what is being claimed. In re Tanczyn,...[347 F.2d 832, 146 USPQ 298 (CCPA 1965)]. [Emphasis in the original.]

Thus, WO 021084381 is not 102(a) prior art to claims 216-226. Therefore, WO 021084381 is not prior art. Therefore, claims 216-226 should not be rejected based upon WO 021084381 and Lee.

In view of the foregoing, the applicant requests that this application be allowed.

4/11/2007

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Date

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Date time code: April 13, 2007 (4:48pm)

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